

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

**In- Vivo Bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Co. (Gly-Once® 1000 mg ER Tablet) with brand drugs (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany ) in Iranian healthy volunteers.**

### Protocol summary

#### Study aim

In- Vivo Bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Co. (Gly-Once® 1000 mg ER Tablet) with brand drugs (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany ) in Iranian healthy volunteers.

#### Design

In-vivo bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Pharma in comparison with reference drug (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany).The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

#### Settings and conduct

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 24 hours with a two-week wash-out period.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-55 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction.

#### Intervention groups

Single dose Metformin ER tablets1000 mg Kooshan Pharmed Pharma. Control group: Single dose Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany

#### Main outcome variables

Plasma drug concentration

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200105046010N70**

Registration date: **2022-10-20, 1401/07/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-10-20, 1401/07/28**

Update count: **0**

#### Registration date

2022-10-20, 1401/07/28

#### Registrant information

##### Name

Javad Shokri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3661 4125

##### Email address

shokri.j@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-10-17, 1401/07/25

#### Expected recruitment end date

2023-06-15, 1402/03/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

**Scientific title**  
In- Vivo Bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Co. (Gly-Once® 1000 mg ER Tablet) with brand drugs (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany ) in Iranian healthy volunteers.

**Public title**  
In-vivo Bioequivalence Test of Metformin ER tablets1000 mg Kooshan Pharmed with brand drug (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, German)

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old  
**Exclusion criteria:**  
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the dru

**Age**  
From **18 years** old to **55 years** old

**Gender**  
Both

**Phase**  
Bioequivalence

**Groups that have been masked**

- Care provider

**Sample size**  
Target sample size: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For this purpose, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Candidates are not aware of receiving the test drug or brand one. In a single study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test drug.

**Placebo**  
Not used

**Assignment**  
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2022-10-10, 1401/07/18

#### Ethics committee reference number

IR.TBZMED.REC.1401.616

## Health conditions studied

### 1

#### Description of health condition studied

Bio equivalence test

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Plasma drug concentration

#### Timepoint

Sampling times in this study will be 0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 10 ,8, 12 , 24 hours after prescribing the tablet.

#### Method of measurement

High Performance Liquid Chromatography with tandem mass spectroscopy detector

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:One test tablet ( Metformin ER tablets1000 mg Kooshan Pharmed) will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the

concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

**Category**

Treatment - Other

**2**

**Description**

Control group: One Reference tablet Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of drug in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Javad Shokri

**Street address**

No.48, Ferdos square

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5167874434

**Phone**

+98 41 3384 2724

**Email**

Shokri.j@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Koushan Pharmed Pharmaceutical Company

**Full name of responsible person**

Delaram Amini

**Street address**

No.15, Padidar Alley, Africa Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1518943814

**Phone**

+98 21 8819 7148

**Email**

CRM@koushanpharmed.com

**Web page address**

<http://www.koushanpharmed.com>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Koushan Pharmed Pharmaceutical Company

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Persons

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Javad Shokri

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, University of Medical Sciences, Daneshgah Street, Tabriz East Azerbaijan

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166414766

**Phone**

+98 41 3334 8489

**Email**

Shokri.j@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Dariush Omidfar

**Position**

Lab. Manager

**Latest degree**

Master

**Other areas of specialty/work**

Bioanalysis

**Street address**

No.48, Ferdos square

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5167874434

**Phone**

+98 41 3384 2724

**Email**

Dariush.omidfar@gmail.com

**Province**

East Azarbaijan

**Postal code**

5167874434

**Phone**

+98 41 3384 2724

**Email**

ahad.sheikhloo@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Ahad Sheikhloo

**Position**

Official Manager

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

**Street address**

No.48, Ferdos square

**City**

Tabriz

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

All information and data of the study will remain secured based on the agreement established between researcher and drug producer

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available